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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/558,474	04/25/2000	J. Fernando Bazan	15631-004810US	8812

28008 7590 11/12/2002

DNAX RESEARCH, INC.
LEGAL DEPARTMENT
901 CALIFORNIA AVENUE
PALO ALTO, CA 94304

EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 11/12/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/558,474

Applicant(s)

BAZAN, J. FERNANDO

Examiner

Olga N. Chernyshev

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-10,21,23-25,27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 8-10,21,23-25,27 and 28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 09, 2002 has been entered.

Response to Amendment

1. Claims 22 and 26 have been cancelled and claims 8, 9, 21 and 25 have been amended as requested in the amendment of Paper No. 17, filed on September 09, 2002. Claims 8-10 and 21, 23-25, 27 and 28 are pending in the instant application.
2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed on September 09, 2002 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

5. Claims 8-10, 21, 23-25 and 27 stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible

Art Unit: 1646

utility for those reasons of record as applied to claims 28 8-10 and 21-28 in section 3a of Paper No.8 and further in section 5 of Paper No. 12. Briefly, because the instant specification does not disclose the biological role or significance of the novel IL-B30 protein, a method for the detection of a polynucleotide that encodes IL-B30 or a kit that contains a probe that hybridizes to such polynucleotide do not have credible substantial practical utility.

Applicant traverses the rejection by referring to the sections of MPEP, which state that “evidence [of asserted utility] will be sufficient if [...] the asserted utility is more likely to be true” (page 5, first paragraph of the Response), and that “an applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. 101 and 35 U.S.C. 112” (page 5, fourth paragraph). The Examiner maintains the position that the instant specification failed to disclose any specific, credible or substantial utility for the instant IL-B30, therefore the it has been concluded that the requirements for 35 U.S.C. 101 were not met in the instant specification.

Applicant further submits that “the Office action overlooked the utilities that were actually disclosed in the present invention” (page 5, last paragraph). Applicant is advised that the reference to Col. 11, lines 43-49 and Col. 25, lines 55-62, where actual experimental data allegedly is being disclosed (page 6, first paragraph), is confusing, for it is not clear what “Col.” refers to in the instant specification. Nevertheless, it is clear that the only experimental data disclosed in the instant specification is limited to cellular expression of IL-B30 (pages 53-59 of the instant specification). The results of the presented data indicate that IL-B30 is expressed in numerous cell lines, several types of primary peripheral blood cells, epithelial cells and splenocytes. Applicant’s argument that “[t]hese experimental data indicate that IL-B30 is at least

Art Unit: 1646

useful as a marker for these immunologically important cell types” (page 6, first paragraph of the Response) is not persuasive because according to the information on page 55, lines 9-35 of the instant specification, IL-B30 was detected in monocytes as well as in splenocytes, epithelial cells and numerous other cell types, and, therefore, cannot be used as “a marker of activated macrophages and dendritic cells” (page 7, last paragraph). Thus, based on the information provided, one would reasonably conclude that at the time the invention was made credible utility of IL-B30 as a specific marker for a specific cell type was not established.

Applicant further submits that the references provided by the Examiner to support the statement regarding credibility of predicting protein functions from structural similarities or homology to the known proteins relate to general technical fields (page 8) and “at most suggest that homology-based functional predictions may not always be accurate” (page 7, last paragraph of the Response). Applicant underlines that “the specification teaches that IL-B30 can play a role in inflammation and a number of other cellular activities” (page 9, first paragraph), which is confirmed in the two post-filing date publications. These arguments have not been found to be persuasive for the following reasons.

The text on page 56, lines 23-29, of the instant specification clearly states that “the distribution shows IL-B30 elevated in activated macrophages, suggesting a role in inflammation”. Mere suggestion of a role in such a broad physiological process as inflammation does not constitute an assertion of a specific, credible and substantial utility of IL-B30. While it is true that “an applicant does not need to show the underlying mechanism of his invention” (page 9, last paragraph of the Response), it is imperative that at the time the application was filed Applicant’s invention is completed and the practical utility of the instant invention is established.

Art Unit: 1646

Applicant's reliance to the Wiekowski et al. publication, which indicates "that just altering IL-B30 expression levels could lead to various cellular and immunological responses in vivo" is not persuasive because until it is disclosed what role IL-B30 plays in "various cellular and immunological responses in vivo", Applicant's claimed invention is incomplete.

Thus, because the instant specification does not disclose a credible specific and substantial utility for IL-B30, then the claimed method for the detection of a polynucleotide, which encodes IL-B30 peptide is not considered to be particular useful, and, therefore, the claimed invention does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

6. Claims 8-10 and 21-28 stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7. Claim 28 stands rejected under 35 U.S.C. 112, second paragraph. Claim 28 is indefinite, see reasons of record in section 7 of Paper No. 12. Briefly, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. In the present instance, claim 28 recites "25, 45, 55 or 60 contiguous nucleotides of SEQ ID NO: 3".

Conclusion

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Application/Control Number: 09/558,474

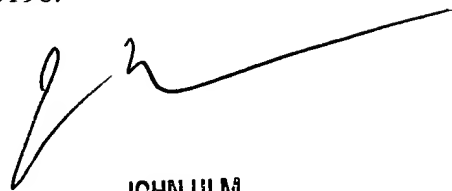
Page 7

Art Unit: 1646

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
November 7, 2002

OC

A handwritten signature in black ink, appearing to read 'John ULM', written over a horizontal line.

JOHN ULM
PRIMARY EXAMINER
GROUP 1800